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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/973,424	10/09/2001	Sudhirdas K. Prayaga	15966-585CIP2 (Cura-85CIP)	8925
30623	7590	12/15/2003	EXAMINER	
MINTZ, LEVIN, COHN, FERRIS, GLOVSKY AND POPEO, P.C. ONE FINANCIAL CENTER BOSTON, MA 02111			ANDRES, JANET L	
			ART UNIT	PAPER NUMBER
			1646	

DATE MAILED: 12/15/2003

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

09/973,424

Applicant(s)

PRAYAGA ET AL.

Examiner

Janet L. Andres

Art Unit

1646

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 12 September 2003.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1,2,4,27,28,33,36,39,49 and 50 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1,2,4,27,28,33,36,39,49 and 50 is/are rejected.
- 7) ☒ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. §§ 119 and 120

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. _____.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
* See the attached detailed Office action for a list of the certified copies not received.
- 13) ☒ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application) since a specific reference was included in the first sentence of the specification or in an Application Data Sheet. 37 CFR 1.78.
a) ☐ The translation of the foreign language provisional application has been received.
- 14) ☒ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121 since a specific reference was included in the first sentence of the specification or in an Application Data Sheet. 37 CFR 1.78.

Attachment(s)

- 1) ☐ Notice of References Cited (PTO-892) 4) ☐ Interview Summary (PTO-413) Paper No(s). _____
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948) 5) ☐ Notice of Informal Patent Application (PTO-152)
- 3) ☒ Information Disclosure Statement(s) (PTO-1449) Paper No(s) 5,12/02. 6) ☒ Other: sequence alignment.

DETAILED ACTION

Election/Restrictions

1. Applicant's election without traverse of Group I, polypeptides and methods of use, and SEQ ID NO:66 in the response filed 12 September 2003 is acknowledged. Claims 1, 2, 4, 27, 28, 33, 36, 39, 49, and 50 are pending and under examination in this office action.

Specification

2. The title is objected to because of the use of the word "novel". Novelty is a legal concept and does not describe the invention claimed. Novelty is required of all claimed inventions before they are issued as patents. To use the term in the title would imply merit in this regard without actual examination. Accordingly, though MPEP 606.01 does not specifically refer to "novel", it is similar to the term "improve" which also implies merit without examination. Note that MPEP 606.01 gives the examiner the final authority to change the title as she sees fit.

Claim Rejections - 35 USC § 102

3. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

4. Claims 1, 33, 36, and 50 are rejected under 35 U.S.C. 102(b) as being anticipated by Chen et al., Oncogene, 1991, vol. 6, no. 6, pp. 1057-1061.

Chen et al. teaches human eek. Chen et al. provided only a partial sequence. However, the complete sequence of eek is identical to Applicant's SEQ ID NO: 5, as is stated on p. 10 of the parent application 09/687726. The amino acid sequence of a protein is an inherent property

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of that protein; specifying the sequence does not change the nature of the protein. SEQ ID NO: 66 is a truncated version of SEQ ID NO: 5. See the sequence alignment provided between eek and SEQ ID NO: 66. Chen et al. thus anticipates claims drawn to sequences comprising SEQ ID NO: 66. While Chen does not specifically teach a carrier, as claimed in claim 33, an expressed protein would of necessity be in some form of carrier. The requirement of a kit, as claimed in claim 36, does not change the nature of the contents of the kit and thus does not distinguish over the prior art of Chen et al.

Claim Rejections - 35 USC § 112

5. The following is a quotation of the first paragraph of 35 U.S.C. 112:

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

6. Claims 2, 4, and 39 are rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement. The claim(s) contains subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention.

These claims are drawn to naturally occurring variants. Such variants exist in nature and have particular sequences, which cannot be predicted. Applicant has disclosed no such variants and one of skill would not, based on the instant specification, be able to identify naturally occurring variants. Thus the skilled artisan would not conclude that Applicant was in possession of such variants.

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7. Claims 27, 28, 39, and 49 are rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the enablement requirement. The claim(s) contains subject matter which was not described in the specification in such a way as to enable one skilled in the art to which it pertains, or with which it is most nearly connected, to make and/or use the invention.

The factors to be considered have been summarized as the quantity of experimentation necessary, the amount of direction or guidance presented, the presence or absence of working examples, the nature of the invention, the state of the prior art, the relative skill of those in the art, the predictability or unpredictability of the art and the breadth of the claims. *Ex Parte Forman*, (230 USPQ 546 (Bd Pat. App. & Int. 1986)); *In re Wands*, 858 F.2d 731, 8 USPQ 2d 1400 (Fed. Cir. 1988).

These claims are drawn to methods of therapeutic use of the polypeptide of SEQ ID NO: 66. The specification, however, fails to provide guidance as to how this protein could be used in any way. What is taught on p. 28 is that message is expressed in several cell types, and differentially expressed in cancerous breast and lung tissue when compared to normal tissue. These teachings provide no indication of how the protein could be used in any therapeutic manner. No relevant biochemical or physiological effects are set forth and there is no direction as to how they could be identified. The prior art fails to provide compensatory teachings; while ephrin receptors are known, what is known primarily concerns their roles in development. No therapeutic use or associated disease is identified by the prior art. Thus, without further guidance, one of skill in the art would not predictably be able to use the protein of SEQ ID NO: 66 in any therapeutic fashion, and it would require undue experimentation to practice the invention as claimed.

NO CLAIM IS ALLOWED.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Janet Andres, Ph.D., whose telephone number is (703) 305-0557.

The examiner can normally be reached on Monday through Friday from 8:00 am to 5:30 pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Yvonne Eyler, Ph.D., can be reached at (703) 308-6564. The fax phone number for this group is (703) 872-9306 or (703) 872-9307 for after final communications.

Communications via internet mail regarding this application, other than those under U.S.C. 132 or which otherwise require a signature, may be used by the applicant and should be addressed to jyvonne.eyler@uspto.gov.

All Internet email communications will be made of record in the application file. PTO employees do not engage in Internet communications where there exists a possibility that sensitive information could be identified or exchanged unless the record includes a properly signed express waiver of the confidentiality requirements of 35 U.S.C. 122. This is more clearly set forth in the Interim Internet Usage Policy published in the Official Gazette of the Patent and Trademark Office on February 25, 1997 at 1195 OG 89.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the Group receptionist whose telephone number is (703) 308-0196.

Janet Andres, Ph.D.
Patent Examiner

December 11, 2003


JANET ANDRÉS
PATENT EXAMINER